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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,002	03/11/2002	Wayne Douglas Luke	X-11506	6427
25885 7	590 01/21/2003			
ELI LILLY AND COMPANY			EXAMINER	
PATENT DIV	8		TUCKER, ZACHARY C	
INDIANAPOLIS, IN 46206-6288			ART UNIT	PAPER NUMBER
			1624	C
			DATE MAILED: 01/21/2003	4

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N .	Applicant(s)			
Offic Action Summary		10/088,002	LUKE, WAYNE DOUGLAS			
		Examin r	Art Unit			
		Zachary C. Tucker	1624			
	The MAILING DATE f this communication appears on the cover sheet with th c rrespondence address Period f r Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status	Decreasive to communication(s) filed on					
1) <u>□</u> 2a)□	Responsive to communication(s) filed on	—· s action is non-final.				
· —	·—		t accountion on to the morite in			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>						
4)⊠ Claim(s) <u>1-15</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.					
6)⊠	6)⊠ Claim(s) <u>1-15</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/or	election requirement.				
Application	on Papers					
9)☐ The specification is objected to by the Examiner.						
10) 🔲 7	he drawing(s) filed on is/are: a)☐ accept	ted or b)⊡ objected to by the Exar	miner.			
. ===	Applicant may not request that any objection to the					
11)[1	he proposed drawing correction filed on		ved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>						
Attachment(s)						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)			

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#### **DETAILED ACTION**

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,631,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

- 1. The "base" specified in claim 1 of 5,631,369 is defined as being preferably potassium carbonate in col. 5, lines 13-21 of that patent, therefore it is an obvious variation of the "inorganic base" specified in instant claim 1.
- 2. As is set forth *infra*, in the rejection of claims 1-15 under 35 U.S.C. 102(b), the presence of hydrated potassium carbonate is inherent in a disclosure of any process wherein anything but freshly prepared anhydrous (calcined) potassium carbonate is employed in a completely non-aqueous milieu.

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3. Claims 2-4, 6 and 8 of US 5,631,369 further limit the type of solvent and base recited in claim 1 of that patent, all of which are specified in instant claims 1-12. Claims 5 and 7 of US 5,631,369 particularly correspond to instant claims 3 and 4, respectively.

Claims 13 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,750,688. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

- 1. As is stated *supra* and further set forth *infra* the "base" specified in claim 1 of US 5,750,688 (which is a division of US 5,631,369) is an obvious variation of the "inorganic base" specified in instant claim 1, from which instant claim 13 ultimately depends.
- 2. Though claim 1 of US 5,750,688 does not specify the step of converting the benzoic acid derivative to an acyl halide with an acyl halide forming agent, the presence of such a step is necessary and clearly is part of the process of claim 1 of US 5,750,688, as example 14 of that patent discloses thionyl chloride. The benzothiophene intermediate will not react with the carboxylic acid formed in step c) of claim 1 in US 5,750,688; the carboxylic acid must be first converted to the acid chloride in order for the acylation reaction to occur.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 699 672 (Kjell et al) or US 5,631,369 (Kjell et al).

Kjell et al, both documents, disclose the same processes as are specified in instant claims 1-15. The EP publication and the US patent are the same disclosure, both based on US application serial number 08/298,636. Since the EP reference was published at an earlier date, what is referred to below, in the explanation of the rejection under 35 U.S.C. 102(b), is that publication. All citations to passages in the EP publication that are made hereinbelow apply equally to US 5,631,369, however they are present on a different page due to US patents being printed in a two-column format.

The presence of a *hydrated* potassium carbonate as the basic reagent in the step of reacting a β-chloroethylamine compound with a 4-hydroxybenzoic acid ester is not expressly stated, however the presence of hydrated potassium carbonate is inherent in the disclosure of Kjell et al.

Unless potassium carbonate is calcined (at 130-160°) to remove all water of hydration, and then *immediately* employed as a reagent (in a completely anhydrous milieu), some hydrated potassium carbonate is always necessarily present therein.

Page 8, lines 23-27 of the Kjell et al publication state that potassium carbonate is the preferred base for the o-alkylation of a hydroxybenzoic acid ester in the process disclosed therein. In the absence of any reference whatever to there being a necessity

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for the potassium carbonate to be totally anhydrous, it is implicit that ordinary, commercially available potassium carbonate is what is being referred to.

Potassium carbonate is a hygroscopic substance, and on standing for any amount of time, will spontaneously absorb water from ambient humidity present in air. In particular, it is the sesquihydrate of potassium carbonate that forms on standing. Page 7, lines 9-18 of the instant specification state that potassium carbonate sesquihydrate (K<sub>2</sub>CO<sub>3</sub>·1.5H<sub>2</sub>O) is consistent with the definition of a hydrated inorganic base containing from 1 to 20% of water.

The English abstract of Dvoinov et al, "Phenomenon of the Caking of Potash"

Trudy Instituta - Moskovskii Khimiko-Tekhnologicheshkii Institut imeni D. I. Medeleeva,
vol. 73 pages 21-23 (1973) is provided herewith to show that the presence of some

K<sub>2</sub>CO<sub>3</sub> · 1.5H<sub>2</sub>O is inherent in the Kjell et al publication's synthetic scheme (examples 1 and 2 on pages 10 and 11 of Kjell et al).

Page 8, lines 30-58 of Kjell et al disclose the limitations further specified in claims 2 and 12 (extracting with aqueous HCl and cleaving the ester).

Example 2 of Kjell et al discloses the process of claim 1 wherein the solvent is isopropyl acetate. Example 2 of Kjell et al discloses all of the limitations of claim 1, in addition to the above-stated line of reasoning (inherency), because 60ml of water is added to the potassium carbonate "to dissolve the potassium carbonate." Addition of bulk water is specified in claim 8, and set forth on page 7, lines 9-18 of the instant specification as one of the ways to provide the hydrated inorganic base recited in instant claim 6.

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Example 14 (pages 14-15) of Kjell et al discloses the process of claim 13.

Thionyl chloride is the reagent employed to form the acid chloride of 4-(2-piperidinoethoxy)-benzoic acid hydrochloride (top of page 15) in that example.

#### Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (703) 305-2050. The examiner can normally be reached Monday-Friday from 7:00am to 3:30pm. If Attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mukund Shah, can be reached at (703) 308-4716. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556 for regular communications and (703) 308-4242 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

zt

Supervisory Patent Examiner

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